

# GlaxoWellcome

March 31, 2000

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Food and Drug Administration  
HFA-305, Room 1-23  
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Rockville, MD 20852

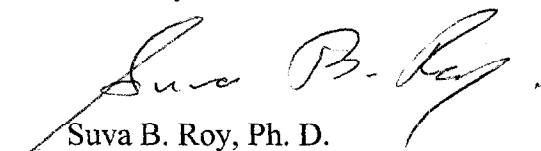
**Re: Docket Number: 00D-0084**

Dear Sirs:

Please find enclosed GlaxoWellcome's comments on the draft Guidance for Industry – Special Protocol Assessment. Our comments relate only to the stability study protocol assessment provisions of this draft guidance.

Please feel free to contact me at (919) 483-6408 if you need additional information or clarification regarding the comments.

Sincerely,



Suva B. Roy, Ph. D.  
Director, Chemistry Pharmacy and Manufacturing  
Regulatory Affairs and Quality Division

00D-0084

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## **Comments from GlaxoWellcome on the Draft Guidance for Industry - Special Protocol Assessment**

### **General Comments**

The following comments relate only to the stability study protocol assessment provision of the draft guidance.

### **Specific Comments**

**Line 83** - A definition for a "standard stability protocol" or a cross-reference to a guidance defining a standard stability protocol would be useful.

**Lines 84- 85** – Examples of what types of changes would be considered "significantly different" with respect to stability protocol would be helpful.

Also, would other changes in CMC between EOP2 meeting and Phase 3 IND, for example, virus validation for biologics considered a significant difference requiring a special protocol assessment?

**Lines 87- 88** – Product characterization studies are clearly defined in the draft Inhalation Products MDI/DPI draft guidance. While some attributes may be characterized prior to initiation of NDA studies, most characterizations are completed on the NDA stability batches. In recognition of this we suggest inserting "critical or key" in the sentence. The revised sentence to read as "The product should be in phase 3 development and *critical or key product* characterization should be complete."

A similar situation often exist for biologics we suggest that the guidance also recognize the same limitation for these drugs.

**Lines 147-150** – We suggest adding the sentence "If the information is contained in the IND it may be cross-referenced."

**Lines 180- 187**- It appears that every time a change is made to a protocol by the sponsor either at the request of the FDA or on their own accord, the 45 day review clock starts anew. Even a single resubmission cycle can result up to a 90day delay in starting the protocol.

Perhaps the section can be rewritten to allow for minor modifications without restarting the review clock and also shorten the review clock on resubmissions containing major amendments made at the request of the FDA.

**Lines 204 – 206** - Often teleconference or a videoconference is faster to arrange than a face-to-face meeting. We suggest that the guidance include the option of requesting a Type A meeting that can be a teleconference or a videoconference.

**Lines 239 – 242** – The drug development process is ever changing, even with the best intentions it may not always be possible to present complete facts. In recognition of this reality we suggest revising the sentence to read as "If based on the data available at that time assumptions or information provided by the sponsor in a request for special protocol assessment change are found to be false statements or misstatements, or are found to omit facts, the Agency will not be bound by any assessment that relied on such data, assumptions, or information."

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